AN HISTORICAL REVIEW OF THE 2009 A (H1N1) INFLUENZA PANDEMIC
AND THE PHENOMENON SURROUNDING VACCINE DECLINATION
BY HEALTH CARE PROVIDERS

By

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Many hands guided me along my path
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I owe my accomplishment to many...

Kelly Keys
To the faculty of Washington State University:

The members of the Committee appointed to examine the project of KELLY ALEEN KEYS find it satisfactory and recommend that it be accepted.

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Preventative health care is not a new concept and since the development of vaccines against communicable diseases, Health Care Providers (HCPs) have willingly received immunizations and lead the way in educating patients about the importance of prophylactic inoculation. Vaccines have improved public safety, lowered patient morbidity and mortality and reduced the financial burden on health care systems. HCPs recognize the importance of this health promotion modality, however, the 2009 flu season found many HCPs unwilling to receive the A (H1N1) vaccine. The right of institutions to mandate seasonal influenza vaccine and the right of HCPs to refuse these immunizations created a quandary. This paper provides an historical account of the 2009 A (H1N1) influenza season and the phenomenon surrounding the declination of the flu vaccine by HCPs.
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An Historical Review of the 2009 A (H1N1) Influenza Pandemic and the Phenomenon Surrounding Vaccine Declination by Health Care Providers

The A (H1N1) pandemic scare of 2009 presented many challenges for Health Care Providers (HCP), including whether or not to accept immunization coverage. Early in the 2009 predicted influenza pandemic, global communications within the World Health Organization (WHO) rallied a heightened alert as compiled data suggested that the A (H1N1) virus was an influenza strain previously unknown to humans (Garten, et al., 2009). It eventually became apparent that A (H1N1) was a “triple-reassortant combination of avian, human, and swine viral gene segments… that was exhibiting a unique epidemiological factor that signified a potential for severe disease” (Swedish, 2010, p. 1). This influenza was unlike any previously observed and scientists feared that the new mutation would strike an antibody naive public, potentially causing the extreme mortality seen in past influenza pandemics. International laboratories rushed to create a vaccine in hopes of providing immunizations that would prevent a repeat of the devastation caused by historical flu pandemics such as the one in 1918 (Babcock, Gemeinhart, Jones, Duncan & Woeltje, 2010; Zimmer & Burke, 2009).

Influenza Background Information

In 1918, it was noted that humans and pigs were exhibiting the same flu like symptoms and this particular strain of influenza, dubbed the Swine Flu, spread worldwide and killed an estimated 40 to 50 million people (Zimmer & Burke, 2009). Similarities in clinical presentation and pathologic features exhibited in both pigs and humans suggested that there had been a transfer of disease between species. The scientific community embarked on research, surveillance and data collection and discovered people exposed to Swine Flu were somehow protected from re-infection of subsequent flu strains. Continued serological studies from the
1930’s showed that serum from subjects who had been exposed to Swine Flu could neutralize the virus in test animals (Zimmer & Burke, 2009). Viral research also discovered that the virus could mutate, taking on characteristics that created a more virulent strain of influenza. The new mutations were able to infect an antibody naive public and this pattern of worldwide influenza epidemic would emerge twice more in the 20th century, (Zimmer & Burke, 2009; Swedish, 2010).

**Pandemics and Antigen Shift**

A total of three worldwide pandemic outbreaks of influenza occurred in the 20th century in 1918, 1957, and 1968. By the time the last two major outbreaks occurred, modern science had developed the capability to differentiate the virus. Three core viral strains were identified as Spanish, Asian and Hong Kong and categorized by the antigenic subtypes of influenza A virus: H1N1, H2N2, and H3N2. These influenza viruses heralded new combinations of antigens that were mutations from previously known strains; the difference arising from a major shift in the HA antigen (Swedish, 2010).

Mutant changes, called antigen drifts, happen when there is a shift in the “antigenicity” of a virus, and that shift causes a recombination of the genomes on the molecular level creating a spliced combination of two or three viral strains. The “antigenic shift is seen only with influenza A viruses and usually results from the replacement of the hemagglutinin (the viral attachment protein that also mediates the entry of the virus into the cell)” (Treanor, 2004, p. 218). The consequence of this type of new antigen integration is a precursor to a pandemic and according to Kilborn (2006) “major influenza epidemics show no predictable periodicity or pattern, and all differ from one another” (p. 1) giving influenza A the highest probability for serious consequences.
Surveillance and Development of Flu Vaccine

Countries have become more closely linked through global trading and international travel, so the potential for global pandemic infection is historically higher than ever before. In recognition of this fact, various global networks work in concert to share new data about influenza viral changes and newly discovered viral locations. The Intergovernmental meeting on Pandemic Influenza Preparedness: Sharing of influenza viruses and access to vaccine and other benefits held on 21-23 November 2007 reinforced the need to use the WHO developed Global Influenza Surveillance Network (GISN). In 2009 GISN was well prepared to provide global tracking information of A (H1N1) influenza specimens and report on mutated viruses surfacing at various global proximities (Fiore, et al., 2010; Moore, et al., 2008).

Differences between Seasonal Flu and Pandemic Flu

According to the Center for Disease Control (CDC) each year in the United States there are, on average, more than 36,000 deaths and 200,000 hospitalizations associated with the seasonal influenza virus (CDC, 2010a). The seasonal flu pattern does not deviate too radically and there is some amount of predictability within current seasonal flu trends. In pandemic flu, there seems to be no predictable pattern, which makes influenza outbreaks a major public health concern (Swedish, 2010). There are differences between seasonal and pandemic influenza with the 3 major differences being 1.) the relative unavailability of vaccine specific to the newly mutated strain of virus, 2.) the immune naivety of the public and 3.) the unpredictable heightened severity of influenza sequelae (Flu.gov, 2011). A more complete list of the pandemic influenza and seasonal influenza differences are shown in Table 1.
<table>
<thead>
<tr>
<th><strong>Seasonal</strong></th>
<th><strong>Pandemic</strong></th>
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<tr>
<td>Seasonal outbreaks follow predictable seasonal pattern, usually winter in temperate climates</td>
<td>Pandemic occurs rarely (three times in 20th century—last in 1968)</td>
</tr>
<tr>
<td>Usually some immunity built up from previous exposure</td>
<td>No previous exposure; little or no pre-existing immunity</td>
</tr>
<tr>
<td>Healthy adults not usually at risk; the very young, elderly or with comorbidities are more vulnerable</td>
<td>Healthy people may be at increased risk for serious complications</td>
</tr>
<tr>
<td>Health systems can usually meet public and patient needs</td>
<td>Health systems may be overwhelmed</td>
</tr>
<tr>
<td>Vaccine developed based on known flu strains and available</td>
<td>Vaccine probably would not be available in the early stages of a pandemic</td>
</tr>
<tr>
<td>Adequate supplies of antivirals are usually available</td>
<td>Effective antivirals may be in limited supply</td>
</tr>
<tr>
<td>Average U.S. annual deaths are approximately 36,000</td>
<td>Number of deaths could be quite high (e.g., U.S. 1918 death toll approximately 675,000)</td>
</tr>
<tr>
<td>Symptoms: fever, cough, runny nose, muscle pain. Deaths often caused by complications, such as pneumonia</td>
<td>Symptoms may be more severe and complications more frequent</td>
</tr>
<tr>
<td>General causes modest impact on society (e.g., some school closing, encouragement of people who are sick to stay home)</td>
<td>May cause major impact on society (e.g., widespread restrictions on travel, closings of schools and businesses, cancelation of large public gatherings)</td>
</tr>
<tr>
<td>Manageable impact on domestic and world economy</td>
<td>Potential for severe impact on domestic and world economy</td>
</tr>
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Flu.gov [http://www.pandemicflu.gov/season_or_pandemic.html](http://www.pandemicflu.gov/season_or_pandemic.html)
Hemispheric Seasonal Influence

Seasonal flu is also dictated in part by climate, with peaks generally occurring in the fall and winter months. Hemispheric tracking and timely international surveillance helps to relay current statistical data and information to global partners in the next targeted areas of infection. For instance, during the duration of any flu season, influenza trends in the southern hemisphere can provide data pertinent to the upcoming flu season for the northern hemisphere and vice versa. Through trend data, decisions can be made for the development of effective vaccine that will target the virus genome type that is most likely to surface. This in turn, helps scientists to develop the most effective vaccine that will provide immunization to the public against the expected seasonal flu strain (Swedish, 2010, CDC b, 2010).

By monitoring the flu types through communicable disease surveillance at the global level, GISN was able to provide necessary information on the communicability of the A (H1N1) virus in 2009. This global surveillance served as an early warning system, providing the rationale for public health intervention. In 2009, this hemispheric global surveillance provided valuable information to the scientific community that helped determine when to implement immediate public health intervention designed to curb morbidity and mortality, (Miller, 2009).

Phases of Pandemic Development

The six-phased model, Diagram 1, was used to categorize and gauge the severity of the 2009 A (H1N1) influenza. This model allowed for earlier recommendations by WHO concerning the actions needed to preserve public safety. Pre-existing pandemic protocols based on the Influenza Phase Index helped to optimize response plans. WHO (2009) explained that, “phases 1–3 correlate with preparedness, including capacity development and response planning activities, while Phases 4–6 clearly signal the need for response and mitigation efforts” (para. 1).
Phases of Pandemic Influenza, Diagram 1

**Phase 1** no viruses circulating among animals have been reported to cause infections in humans.

**Phase 2** an animal influenza virus circulating among domesticated or wild animals is known to have caused infection in humans, and is therefore considered a potential pandemic threat.

**Phase 3**, an animal or human-animal influenza reassortant virus has caused sporadic cases or small clusters of disease in people, but has not resulted in human-to-human transmission sufficient to sustain community-level outbreaks. Limited human-to-human transmission may occur under some circumstances, for example, when there is close contact between an infected person and an unprotected caregiver. However, limited transmission under such restricted circumstances does not indicate that the virus has gained the level of transmissibility among humans necessary to cause a pandemic.

**Phase 4** is characterized by verified human-to-human transmission of an animal or human-animal influenza reassortant virus able to cause "community-level outbreaks." The ability to cause sustained disease outbreaks in a community marks a significant upwards shift in the risk for a pandemic. Any country that suspects or has verified such an event should urgently consult with WHO so that the situation can be jointly assessed and a decision made by the affected country if implementation of a rapid pandemic containment operation is warranted. Phase 4 indicates a significant increase in risk of a pandemic but does not necessarily mean that a pandemic is a foregone conclusion.

**Phase 5** is characterized by human-to-human spread of the virus into at least two countries in one WHO region. While most countries will not be affected at this stage, the declaration of Phase 5 is a strong signal that a pandemic is imminent and that the time to finalize the organization, communication, and implementation of the planned mitigation measures is short.

**Phase 6**, the pandemic phase, is characterized by community level outbreaks in at least one other country in a different WHO region in addition to the criteria defined in Phase 5. Designation of this phase will indicate that a global pandemic is under way.

During the **post-peak period**, pandemic disease levels in most countries with adequate surveillance will have dropped below peak observed levels. The post-peak period signifies that pandemic activity appears to be decreasing; however, it is uncertain if additional waves will occur and countries will need to be prepared for a second wave.

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2009 A (H1N1) HCP PROPHYLACTIC COVERAGE STARTS THE DEBATE

By early May of 2009, the A (H1N1) mutated virus had entered phase 4. Fear that it would soon enter phase 5/6 hastened the development of an A (H1N1) vaccine with trial testing commencing in the southern hemispheres and Europe. Vaccine production is time consuming and Miller (2009) noted that, “our ability to produce a vaccine in sufficient quantities to cover people who are exposed in a first pandemic wave is very limited with today’s technology,” (p. 2597). Miller surmised that in 1968, “most of the deaths in Europe and Asia could probably have been prevented if an effective vaccine had been available and used even a year after the emergence of the A/H3N2 viruses” (p. 2597) Fearing ramifications of a pandemic, vaccine production was set in motion even though scientists knew that the optimal formulation for the vaccine was still unknown. The CDC monitored vaccine efficacy and its prophylactic ability to secure immunity. Clinical trials in Europe were still in progress when the first batches of vaccine reached the U.S. (Clark, 2009; Zimmer, 2009).

Recommendation for Vaccine Coverage

Timely implementation of immunizations is paramount in order to stop the possibility of world pandemic. When the first A (H1N1) vaccine became available to the U.S., there was insufficient quantity available to cover everyone. Discussion centered around the most efficient use of the A (H1N1) immunizations and the CDC’s Advisory Committee on Immunization Practices (ACIP) initially recommended prioritizing vaccination to five target groups. These groups included vulnerable populations along with emergency medical services personnel and health care providers, (Fiore, et al., 2010; Swedish, 2010). Hospital personal and other care givers were encouraged to get the H1N1 vaccine along with the seasonal flu to protect themselves and their patients.
2009 A (H1N1) VACCINE AND HCP DECLINATION PHENOMENON

Hesitancy on the part of some HCPs to take the H1N1 inoculation created a political backlash that sparked talk of mandatory immunization. As questions were being raised about the legal ramifications of implementing mandatory vaccination, on August 2009, New York State’s health department issued a statewide emergency regulation requiring all HCPs and others who had contact with patients to be vaccinated against A (H1N1), (Stewart, 2009; Swedish, 2010).

Resistance and Backlash

Lawsuits were filed, claiming that the health department had over-stepped its authority and violated individuals’ constitutional rights. To sort out the legal conflicts, the courts had to consider, “constitutional guarantees of personal autonomy, freedom of contract, and freedom of religion when reviewing the current lawsuits” (Stewart, 2009, p. 2017). These constitutional concepts of individual rights were deemed foundational to personal freedoms and yet they seemed in direct conflict with the law’s intent to protect patient safety and maintain community health.

Shortage of vaccine caused the New York courts to rescind the regulation and on October 16, 2009, “a trial court issued temporary restraining orders in two cases, blocking the implementation of the regulation” (Parmet, 2010, p. 1951). Mandating the A (H1N1) immunization became a moot point when WHO declared the 2009 pandemic influenza A (H1N1) to be in the post-pandemic period and that “the new H1N1 virus [had] largely run its course” (WHO, 2010, para. 1). The 2009 A (H1N1) pandemic crisis had passed and yet unanswered questions concerning HCP declination rates still remained.

Measured HCP Compliance and Perception

Research into HCPs’ declination rates for seasonal influenza vaccinations before the 2009 pandemic helped to provide insight into the attitudes, expectations and misunderstandings
that circulated around the 2009 influenza vaccine. Using data collected from the years 2004-2008 National Health Interview Survey, Alberto J. Caban-Martinez (2010) and his research team from the Department of Epidemiology and Public Health at the University of Miami Miller School of Medicine measured the predictors of vaccine non-compliance among healthcare workers.

Additional research reported by Kent, Lea, Fang, Novick and Mordan (2010) investigated the percentage of employees receiving seasonal influenza vaccination, including perceptions and attitudes of employees at 17 health agencies in a 25-county region in eastern, rural North Carolina. Both of these studies reached similar conclusions and Milner’s research (2010) supported these findings, stating that the main explanations for declinations were related to “misconceptions regarding the effectiveness and health risks of the vaccine as well as a belief that the vaccine was unnecessary” (p. 993).

Research Reviewed

Data collected from 6349 U.S. health care workers in the 2004-2008 National Health Survey (NHIS), an annual population-based survey, was analyzed. Results showed that seasonal influenza vaccination coverage remained low among health care workers; reporting the highest rates among the health diagnosing and treating practitioners at 52.3% and the lowest rates among other health care support occupations at 24.7% (Caban-Martinez, et al., 2010). After analysis of the data, Caban-Martinez (2010) concluded that, “there were no significant upward or downward trends in influenza vaccination rates for any healthcare or other occupational worker group during the 5-year survey period,” (p. 211).

A cross-sectional survey conducted in 2007-2008 was administered to 17 health agencies in eastern, rural North Carolina to look at the percentage of HCPs receiving the seasonal influenza vaccine and the perceptions and attitudes regarding the vaccines. Prior to the A (H1N1)
pandemic scare, this voluntary, self-administered survey had a 73% response out of a total of 1653 employees in May of 2008. Findings were analyzed, showing that gender, ethnicity and ≥ 10 years working in the public health field were significantly associated with obtaining the vaccine. Positive predictors for receiving a flu vaccine were having had seasonal vaccine the previous year and perceiving the immunization to be of significant value for personal health while the two biggest deterrents were fear that the influenza vaccine could cause illness and out of pocket cost in instances where employees had to pay for their own vaccines, (Kent, Lea, Fang, Novick, & Mordan, 2010).

Continued investigation in 2009 by Vaughn Milner, PhD and his research team focused on determining the reasons why health care personnel in a public health department chose or refused free influenza vaccinations offered at the work site. The research team tested for differences between vaccinated and non-vaccinated cohorts at a public health nurse site in Mobile, Alabama and of 426 employees surveyed, 311 (73%) responded (Milner, Eichild, Franks & Johnson, 2010). Predictors of vaccine noncompliance were listed as younger age, fear of needles, fear of getting sick from the vaccine, disbelief that the vaccine was effective and ignoring vaccination as a healthy behavior. Milner et al. (2010) concluded that “the non-vaccinated group refused the vaccine primarily for reasons related to misconceptions regarding the effectiveness and health risks of the vaccine, as well as a belief that the vaccine was unnecessary” (p. 993). These findings give insight into some of the reasons behind declinations and found that bias and fear provided the main impetus for refusal, however when a person chooses to serve in health care, should ethics over-ride fear and the right to refuse?
2009 A (H1N1) VACCINE AND HCP DECLINATION PHENOMENON

Ethics

HCPs have a professional obligation to do as much as is reasonably possible to care for their patients and this may include incurring a reasonable amount of personal risk while providing that care. For instance, nurses face risks on the job from infections, violent patients, and many other sources, yet, under the threat of a pandemic, immunization against the A (H1N1) influenza was resisted by HCPs across the U.S. and worldwide, (CDC, 2010c). When discussing the 2009 pandemic scare, mandatory inoculation and the hesitancy of some HCPs to get the A (H1N1) vaccine, Miko and Miller (2009) explained that HCPs should be held to a higher standard, and indeed, should be expected to willingly receive the inoculation. They argued that it was the moral obligation of health care providers and policymakers to “promote the wellbeing of their society… it may be unacceptable and even unethical for them [HCPs] to idly to stand by and do nothing…they must do whatever is “right” and necessary to stop the spread of the virus” (Miko & Milner, 2009, p. 3). This attitude was not a new perception and many health care institutions held to the same ideals.

During the 2009 pandemic scare, New York State was not alone in their efforts to protect the public from unvaccinated HCPs. Several other states had begun looking at the rationale behind mandatory seasonal influenza vaccinations, (Stewart, 2009). Mandating influenza immunizations was not a new concept and in 2008, Barnes-Jewish and St. Louis Children’s Hospitals (BJC) in St. Louis, an 11-hospital system, became the first large health system in the country to require influenza vaccination as a condition of employment.

Acculturate HCPs to Seasonal Flu Vaccine

When discussing other vaccines, such as measles, mumps, and rubella, in 2010, Hilary Babcock, the medical director of Occupational Health at BJC Hospitals, reported that these and
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other mandatory compliance behaviors “are already required by many health care facilities, as is annual tuberculin skin testing [and that] Virginia Mason Hospital (Seattle, WA) implemented a mandatory influenza vaccination program in 2004,” (Babcock, et al., 2010, p.460). Introduction of the concept of seasonal immunization at BCJ facilities was planned carefully and completed through employee letters and educational materials. Giving a sense of empowerment through education and interaction to the employees seemed to help create an environment of acceptance.

One successful strategy used to encourage employee involvement was the implementation of “town meeting” forums provided by the medical facilities where employees had an opportunity to discuss concerns with infection control specialists. Medical exemption requests were reviewed by occupational health nurses and their medical directors. Babcock went on to explain that the vaccination policy in 2009 was quickly accepted by employees at her facilities and including those personnel with medical or religious exemptions, a total of 98% of the system’s 26,000 employees received the vaccine.

By using thoughtful preemptive preparation, BCJ Hospitals were able to realize a high compliance with their HCPs receiving the A (H1N1) immunization, but this was not the case nationwide. When 2009 immunization data became available, the CDC reported that “seasonal influenza vaccination coverage among health-care workers [had] historically been below at 50% [and by] December 2009, only 22% of health-care workers in the U.S. reported having been vaccinated with the A (H1N1) vaccine” (Singleton, 2010, para. 5). Many HCPs were disinclined to receive the 2009 A (H1N1) flu vaccine, even in light of a possible pandemic.

Discussion

When the novel A (H1N1) influenza was first detected in mid-April 2009, the CDC began working with states to collect, compile and analyze information regarding the outbreak. A
CDC model was developed to try to determine the true number of novel H1N1 flu cases in the United States. The model took the number of cases reported by states and adjusted the figure to account for known sources of underestimation (for example; not all people with novel H1N1 flu seek medical care, and not all people who seek medical care have specimens collected by their health care provider). Using this approach, it is estimated that more than one million people became ill with novel H1N1 flu between April and June 2009 in the United States, (CDC, 2009).

Resistance against taking the A (H1N1) vaccine among HCPs was seen as a dangerous stance in light of the gravity of the pandemic ramifications and some states and organizations took steps to mandate inoculation. Lack of vaccine availability and several pending court cases placed the mandatory requirements on hold and investigation into resistance revealed insightful information. Discussion centered on whether the degree of benefit expected for patients outweighed the degree of risk a provider might incur from the vaccine.

Regarding risk, most flu vaccines in the past have had an excellent safety track record overall, (CDC, 2011). Regarding benefit, evidence shows that vaccination of health care workers results in fewer patients getting the flu, (Babcock, et al., p. 1; Simonsen, Viboud,Taylor, Miller & Jackson, 2009) and it is those patients most in need of protection (the elderly, newborn, and the immunocompromised) that vaccination of HCPs protects. No matter how rapidly a safe and effective vaccine is produced, it will be ineffective if large numbers of people refuse to be vaccinated. HCPs, as well as patients, should be afforded the same respect for their decisions about health care, including the right to refuse a treatment that is due to all patients, however, stepping into the role of care giver may supersede anonymity. Certain risks come with the profession of providing health care and that may include receiving a mandatory seasonal influenza vaccination.
Conclusion

Many HCPs are not convinced that seasonal influenza vaccine is personally beneficial and the cumulative evidence about vaccine efficacy and efficiency does not alter the rights of those who are not willing to be vaccinated. More research needs to be done to develop HCP education surrounding vaccine efficacy and safety. Acculturation to participate in volunteer influenza inoculations can be slowly implemented and even then it may be difficult to obtain higher volunteer compliance ratings from HCPs, no matter how improved the message. The potential danger is that current health guidelines and policies in emergency conditions might not be implemented fast enough to thwart another possible influenza pandemic; next time coverage may prove to be too late.
References


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